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Italian version of the Cumberland Ankle Instability Tool (CAIT-I)

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ABSTRACT

Study design: Evaluation of the psychometric properties of a translated, culturally adapted questionnaire.
Objective: Translating, culturally adapting, and validating the Italian version of the Cumberland Ankle Instability Tool (CAIT-I).
Summary of background data: Ankle sprains are one of the most common musculoskeletal injuries and can lead to chronic ankle instability (CAI). The International Ankle Consortium recommends the Cumberland Ankle Instability Tool (CAIT) as a valid and reliable self-report questionnaire assessing the presence and severity of CAI. At this moment, there is no validated Italian version of CAIT.
Methods: The Italian version of the CAIT (CAIT-I) was developed by an expert committee. Test-retest reliability of the CAIT-I was measured in 286 healthy and injured participants within a 4–9-day period, by using Intraclass Correlation Coefficients ($ICC_{2,1}$). Construct validity, exploratory factor analysis, internal consistency and sensitivity were examined in a sample of 548 adults. Instrument responsiveness over 4 time points was determined in a subgroup of 37 participants.
Results: The CAIT-I demonstrated excellent test-retest reliability (ICC$\geq$0.92) and good internal consistency (α = .84). Construct validity was confirmed. Identified cut-off for the presence of CAI was 24.75, with sensitivity= 0.77 and specificity= 0.65. There were significant differences across time for CAIT-I scores ($P < .001$), demonstrating responsiveness to change, but no floor or ceiling effects.
Conclusion: The CAIT-I demonstrates acceptable psychometric performance as a screening and outcome measure. The CAIT-I is a useful tool to assess the presence and severity of CAI.

1. Introduction

Lateral ankle sprain is the most common injury in sports populations [1,2]. The estimated injury rate incidence for ankle sprains per 1000 athlete exposures is 1.05 in males and 1.17 in females [3]. Usual complaints following an ankle sprain are persistent symptoms and a feeling of ankle joint instability. The latter, coupled with reports of 'giving way' episodes of the ankle joint and recurrent injury, represent the characteristic features of chronic ankle instability (CAI) [4,5]. Compared with controls, patients with CAI also have lower levels of physical activity and sports participation [6,7], reduced quality of life [8] and increased risk of developing post-traumatic ankle osteoarthritis [9]. Current management of CAI targets different impairments such as deficits in proprioception, balance, range of motion, and muscle strength [10,11].

Hiller et al. [12] devised the Cumberland Ankle Instability Tool (CAIT). It was originally developed in English and proved to have high content validity and good reliability. The CAIT is designed to evaluate both left and right ankles, making it possible to assess both ankles individually. However, to be used in non-English speaking populations, CAIT requires translation and cultural adaptation in order to maintain the validity of tool content across different cultures [13]. By doing so, CAIT has already been validated in Brazilian-Portuguese, Spanish (twice), Korean, Japanese, Persian, Dutch, French, Arabic, Greek, Taiwan-Chinese, Chinese (twice), and Urdu [14–28].

Questionnaires with adequate psychometric properties can assist in assessing injury severity, recovery, performance readiness for athletic

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activities, planning injury prevention strategies, enhancing individual's well-being and function and guiding the rehabilitation process [29]. In particular, the CAIT questionnaire has proved to be useful as a diagnostic tool in order to discriminate between patients with simple ankle sprains issues and patients with CAI [12]. The CAIT is a reliable and valid questionnaire usable to evaluate CAI in outpatient clinics. Its use in clinical practice has been recommended by the International Ankle Consortium to identify patients with CAI [5].

However, currently, to our knowledge, there is no Italian version of the CAIT. The purpose of this study was to develop a cross-cultural translation and adaptation of the CAIT into the Italian language (CAIT-I) and to validate the CAIT-I in the Italian population, testing its psychometric properties.

2. Methods

The current study was a cross-sectional study of transcultural adaptation and validation in Italian of the CAIT.

The Institutional Review Board of the Institute (*Comitato di Bioetica Alma Mater Studiorum – Università di Bologna*) approved the trial on 2020 April 30th, allowing the development of the CAIT-I. When accessing the questionnaire, all participants provided informed consent for the collection, storage, and processing of their data for the purposes of the study, according to article 13 of the General Data Protection Regulation (GDPR) 2016/679. The protocol of this study was registered on ClinicalTrials.org with the Identifier NCT04644601, Unique Protocol ID: 273082.

2.1. Instruments

The CAIT is a patient-reported outcome measure created to detect perceived ankle instability and can also provide a measure of the severity of it [12]. The assessment takes into consideration nine items that generate a total score ranging from 0 to 30, with lower scores indicating more severe instability and 30 as the best possible score. The original study established a cut-off score of $\leq$ 27.5 to identify the subjects complaining of CAI [12].

Appendix A – CAIT-I.

The Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36)[30,31] has been used to study CAIT-I construct validity. SF-36 measures 8 domains of health-related function, testing both physical and mental health. The domains of the SF-36 include physical functioning (PF), limitations due to physical problems ("role physical", RP), bodily pain (BP), general health perceptions (GH), vitality (VT), social functioning (SF), limitations due to emotional problems ("role emotional" RE), and mental health (MH). Each domain is scored as a *z* score ranging from 0 to 100, with a higher score indicating better health [32]. Standard procedures were used to obtain a physical component summary (PCS) score consisting primarily of PF, RP, BP, and GH-domains and mental component summary (MCS) score consisting primarily of VT, SF, RE, and MH-domains.

2.2. Translation and cross-cultural adaptation

This stage followed the Guidelines for the Process of Cross-Cultural Adaptation of Self-Report Measures [13,33].

Step 1. Forward Translation. CAIT-I was initially translated from English into Italian by two independent translators, whose native language was English. The purpose was to retain the concept of the original scale, using culturally and clinically fitting expressions. One of the translators (called "naïve") was not familiar with the instrument nor the specific medical terminology. Each translator produced a written report of the adaptation they had made. Additional comments were made to highlight challenging phrases or uncertainties. The rationale for their choices was also summarized in a written report.

Step 2. Synthesis. The two translators sat down to synthesise the results of the translations. Based on the original questionnaire as well as the two translator's versions, a synthesis of these was conducted, with a written report carefully documenting the synthesis process, each of the issues addressed, and how they were resolved. Keeping the language colloquial and compatible with a reading age level of 14 years, poorer wording choices were outlined and resolved in a discussion between the two translators. (See Appendix B).

Step 2 ended when a common adaptation was shared. None of the items was excluded.

Step 3. Backward Translation. Two bilingual native Italian-speaking translators backward translated the initial translation. They were selected because they were unaware of concepts explored and without medical background. Considering cultural diversities, conceptual equivalence, and vocabulary differences, the aim was to make sure that the Italian version reflected the same item contents of the original version.

Step 4. Expert Committee. The translated versions were submitted to a bilingual committee composed of three clinicians, two language and communication experts and the four translators. To identify difficulties, inconsistencies or mistakes in translation, the committee explored semantic, idiomatic, experiential, and conceptual equivalence of items and answers options. Step 3 ended when a pre final version was achieved.

Step 5. Test of the Pre-Final Version. The pre-final version was administered to a random sample of 48 Italian-speaking participants, who accepted the team invitation. This sample was composed of people with different cultural and social backgrounds. (See Appendix B).

Each participant was asked to rate the instructions and items of the scale using a dichotomous scale (clear or unclear). Participants who rated the instructions, response format or any item of the instrument as unclear were asked to provide suggestions on how to rewrite the statements to make the language clearer.

Step 6: Full psychometric testing of the translated instrument in a sample of the target population.

The final shared version of the questionnaire (see Appendix A) was used for the validation process. The validation of the psychometric properties of the instrument started after it was administered digitally, via a link to a website (http://www.studio-fv.it/limesurvey/index.php/236527?lang=it) that relied on LimeSurvey, an application based on a MySQL database that allows to create online surveys. The minimum number required was 10 participants for each item of CAIT-I, aged 18 or above, recruited through universities, sport clubs, sports associations, and health professionals. Through this link, from January 7, 2021 to November 16, 2021 the subjects who gave their informed consent to their voluntary participation, were able to access the online questionnaire.

2.3. Participants

Adult volunteers were invited to participate in this study through the recruitment of universities, sports associations, clubs and private practices, or health professionals. Participants were divided into 'healthy' and 'injured'.

Inclusion criteria for 'healthy' participants:

- Age $\geq$ 18 years
- No experience of ankle instability and/or feeling of the ankle giving way in the last 3 months.

Inclusion criteria for 'injured' participants:

- Age $\geq$ 18 years
- At least an episode of ankle sprain during lifetime and perceived ankle instability and/or feeling of the ankle giving way in the last 3 months

Exclusion criteria:

- Inability to understand written Italian language
- Pregnancy
- Having undergone surgery on the ankle-foot area in the last 6 months.

All recruited participants gave their informed consent to the collection, storage and processing of data for the purposes of the study based on international ethical standards for studies in Sport and Exercise Science [34]. Upon enrolment, and after obtaining their consent, participants answered a demographics questionnaire, CAIT-I, and SF-36. If they took part in the reliability portion of the study, they filled out the two questionnaires a second time within 4–9 days.

Sample size for test-retest reliability with one group, two measurements (test-retest), effect size $\delta = 0.50$, power= 0.95, and $\alpha = 0.05$, was determined conducting a priori analysis [35] resulting in 134 participants required (Appendix C). A sample of 286 participants was used in this analysis. To assess construct validity, with one group, effect size $\delta = 0.25$, power= 0.95, and $\alpha = 0.05$, a sample of 54 was required and for factor analysis (Appendix C), 10–15 participants per item are recommended [36,37]. Having a 9-item questionnaire, 90–135 participants were estimated. A sample of 548 participants was used in the construct validity and factor analyses. This same sample of 548 participants was used to assess differences between 'Healthy' and 'Injured' groups in receiver operating characteristic (ROC) analyses, since a total sample of 104 was found necessary, conducting a sample size estimation using a predetermined level of sensitivity of 80 % (H_a=0.80), $H_0 = 0.50$, $\alpha = 0.05$, and power= 0.95 [35,38].

To assess instrument responsiveness, a priori analysis for sample size was conducted using a 1-group repeated-measures analysis of variance over 4 time points: healthy ($T_{healthy}$), after 4–9 days period (T_2), injured at intake at rehabilitation services ($T_{injured}$) and after discharge from rehabilitation services ($T_{discharge}$). With a small effect-size change of 0.25, $\alpha = .05$, and power of 0.95, a total sample of 36 was required (Appendix C). A sample of 37 participants was used in this analysis.

2.4. Data analysis

Demographics, CAIT-I and SF-36 data were entered into a SPSS database (IBM SPSS Statistics, Version 22). Incomplete questionnaires missing more than two items were deleted. For those missing one or two items (less than 5 % of the sample), values were filled-in using mean imputation [39]. CAIT-I scores for left and right ankle were obtained by summing individual question scores. SF-36 scores for the 8-domains and composite PCS and MCS score were obtained using standard procedures [40]. Higher scores for both questionnaires reflected higher function.

2.5. Psychometric scale properties

Acceptability. The time needed to answer the questionnaire was registered. Once completed, examiners checked all data to report missing or multiple responses.

Reliability. Test-retest reliability analysis separately compared 'healthy', 'injured' and 'combined groups' for the CAIT-I scores and ADL and Technique sub scores using the Intraclass Correlation Coefficient, two-way random, single measures, absolute agreement (ICC2,1). ICC values were considered: low $\leq$ 0.49, moderate 0.50–0.69, high 0.70–0.89, and very high 0.90–1.00 [41]. We hypothesised high correlations (ICC$\geq$0.70). Absolute reliability, defined as variability of scores between different administrations reflecting instrument accuracy, was measured using standard error of measurement (SEM) [42,43]. SEM, expressed in the units of original measurement, was calculated from the standard deviation (σ) of measurement error, with the assumption that measurement error is normally distributed: SEM= $\sigma \sqrt{1\text{-}r}$ r = coefficient alpha.

Minimal detectable change (MDC) was also determined [44]. The following formula was used to calculate the individual MDC (MDC_{ind}):

$$MDC_{ind} = SEM \times 1{\cdot}96 \times \sqrt{2}$$

The group MDC (MDC_{group}) was calculated by dividing the MDC_{ind} by the square root of the number of participants in the sample.

Construct Validity. Construct validity was achieved comparing (Pearson correlations) CAIT-I total and items scores to the SF-36 [30,40] PCS, MCS, using Pearson correlation coefficients by SPSS.

Exploratory factor analysis (EFA). The factor structure of the CAIT-I was analysed by means of factor analysis. EFA, a variable reduction technique, was conducted to identify the number of latent constructs and underlying structure using parallel analysis, eigenvalues, scree plots, suppression of small coefficients, and rotation to determine CAIT-I factor structure [45–47]. Cattel Scree Test was used to determine the number of extracted factors (eigenvalues greater than 1) (Fig. 1). We hypothesised a two-factor model.

The quality of the factor analysis was assessed using the Kaiser-Meyer-Olkin Measure of Sampling Adequacy (KMO) and the Bartlett test of sphericity. The KMO evaluates sampling adequacy with a high value indicating that factor analysis is appropriate (>0.70). A significant value $p < 0.05$ indicates data are appropriate and sampling is sufficient. The Bartlett test examines the correlation between items, checking if there is redundancy between variables that could be summarized with some factors. We hypothesised item correlations of 0.50 or greater.

Internal Consistency. Cronbach's α was calculated to estimate internal item consistency. The EFA and Cronbach's α were conducted in open-source software (JASP Version 0.11.1; University of Amsterdam, Amsterdam, the Netherlands). We hypothesised a Cronbach's α of.70 or greater.

Sensitivity. To conduct sensitivity analyses in 'Healthy' and 'Injured' groups, we conducted a t-test for equal variances not assumed, due to unequal sample sizes of each group ('Healthy'=491 and 'Injured'=57), and significant Levene's test ($p < .001$). For this analysis, only the data concerning the ankle with the worst CAIT-I total score for each participant was considered, both for the so-called 'healthy' and the 'injured' ones. Predictive accuracy or sensitivity was measured by generating ROC curves, area under the curves (AUC) and associated 95 % confidence intervals (CI) for the CAIT-I scores (left and right ankle) by SPSS. The ROC curves used CAIT-I scores as test variables with binary state or outcome variable coded as 0 =Healthy and 1 =Injured. Sensitivity and specificity for cut off values were determined. The clinical meaningfulness of the cut-off score was evaluated by calculating the positive likelihood ratio (LR+) and negative likelihood ratio (LR-). The LR+ was calculated as [sensitivity/(1 - specificity)], and the LR- was calculated as [(1 - sensitivity)/specificity].

Internal Responsiveness. To determine internal responsiveness, we

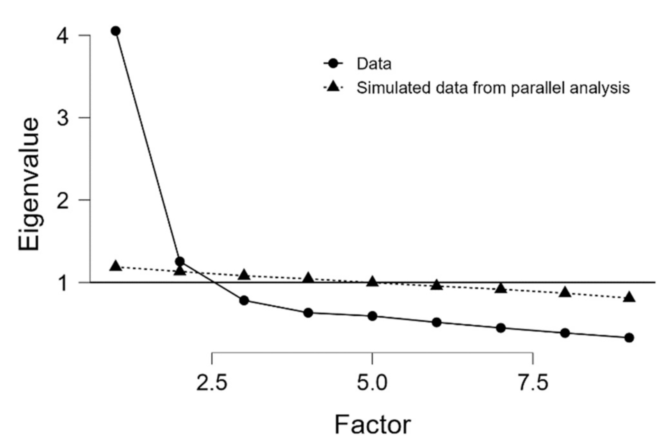

Fig. 1. Scree plot.

examined differences in CAIT-I in 'injured' participants across 4-time points using repeated-measures (time) analysis of variance by SPSS. This analysis took into consideration only the participants who satisfied the requirements for the 'healthy' group during the first questionnaire administration, and then developed an ankle sprain, followed by symptoms of instability. For all analyses, Mauchly's test was used to assess the assumption of sphericity. In the case of significance, the Huynh-Feldt correction was applied to the degrees of freedom and F value if the epsilon value was 0.75 or greater, and the Greenhouse-Geisser correction was used if epsilon was less than 0.75. In these cases, epsilon and corrected values (e.g., degrees of freedom and F values) were reported. Pairwise comparisons were conducted where there was a significant main effect. Given the number of dependent variables, a conservative level of significance was set at $\alpha = .001$. We hypothesised pairwise differences across time points, in particular between $T_{injured}$ (questionnaire filled by participants after having experienced an ankle sprain followed by perceived ankle instability) and all the other administrations ($T_{healthy}$ = baseline, T2 = after 4–9 days, $T_{discharge}$=at the end of the rehabilitation).

Internal responsiveness was defined in 4 ways: SEM, minimal detectable change at the 95 % CI (MDC_{95}), standardised response mean (SRM), and effect size (EF), using the following equations: $MDC_{95} = 1.96 \times \sqrt{2} \times SEM$;.

SRM = mean change in score/SD of changed scores

EF = mean change scores/SD of baseline scores

The SEM, MDC_{95}, SRM, and effect size were calculated for the CAIT-I total scores and for the SF-36 PCS and MCS. We anticipated SRM values of 0.80 or greater, demonstrating high responsiveness [48,49] and large effect sizes (> 1.0). EF values between 0.20 and 0.50 were considered small, 0.51–0.80 medium, and those higher than 0.80 large [50]. For each participant, we used data only for the ankle that exhibited symptoms of instability (in case of a bilateral problem, the worst one).

Floor and ceiling effects. We determined the percentage of participants who achieved the highest and lowest CAIT-I scores within the 'Injured' group. Ceiling and floor effects of < 15 % of respondents scoring the highest or lowest scores were considered acceptable [51].

3. Results

3.1. Acceptability

All the questions were well accepted by the participants. The questionnaire was completed in a mean of 9 min (± 8.19), with a minimum of 2 and a maximum of 22 min.

3.2. Reliability

286 participants took part in the CAIT-I test-retest reliability analysis (156 females, 130 males) (Table 1).

The mean BMI of the sample fell within the healthy weight range. Two hundred of them (90,5 %) declared to exercise regularly (at least 2–5 h/week as recommended by the WHO) and the most practised sports were running (38 %), jogging (34 %), basketball (16 %), yoga/Pilates (13 %), soccer (11 %) and volleyball/beach volleyball (10,5 %). 256 of them reported not to have experienced any episode of ankle sprain in the last 3 months (90,5 %) while 27 (9,5 %) reported at least one episode in the last 3 months. Overall, 54 of them (18,9 %) remembered experiencing at least one main ankle injury during their lifetime, 44 (15,4 %) two episodes and 79 of them (27,7 %) more than 2 episodes.

For combined groups, test-retest reliability values of the CAIT-I scores were excellent ($ICC_{2,1} = 0.93$ for both left and right ankle) (See Table 5 – Supplementary Material - Test-Retest Reliability of the CAIT-I). Investigation at the item level found that test-retest reliability of all items was high (ranging from $ICC_{2,1} = 0.76$–0.87). The SEM values were 2,80 (left ankle) and 3,12 (right ankle). MDC_{ind} were 7.8 for the left ankle and 8.6 for the right one, while MDC_{group} were 0.43 and 0.51 for left and right leg respectively.

Table 1
Demographics (Test-Retest Reliability).

Demographic/Group	Male	Female	Total
Participants, n (%)[a]	130 (45.5 %)	156 (54.5 %)	286 (100 %)
BMI[b]	24.3 ± 2.9	22 ± 3.6	23.0 ± 3.5
Perception of ankle instability in the last 3 months following at least 1 episode of ankle sprain n (%)[a]			
Yes	14 (10.9 %)	13 (8.4 %)	27 (9.5 %)
No	115 (89.1 %)	141 (91.6 %)	256 (90.5 %)
Lifetime Prevalence of Ankle Sprains, n (%)[a]			
1	25 (48.1 %)	27 (51.9 %)	52
2	25 (56.8 %)	19 (43.2 %)	44
> 2	45 (57.0 %)	34 (43.0 %)	79
Do you exercise regularly? n (%)[a]			
Yes	98 (77.2 %)	102 (66.7 %)	200 (71.4 %)
No	29 (22.8 %)	51 (33.3 %)	80 (28.6 %)
If Yes, which Sport do you practice? n (%)[a]			
Running	43 (56.6 %)	33 (43.4 %)	76
Jogging	21 (30.9 %)	47 (69.1 %)	68
Basketball	18 (56.3 %)	14 (43.8 %)	32
Yoga/Pilates	3 (11.5 %)	23 (88.5 %)	26
Soccer	16 (72.7 %)	6 (27.3 %)	22
Volleyball/Beach Volleyball	8 (38.1 %)	13 (68.9 %)	21
Others	74 (54.4 %)	62 (45.6 %)	136

[a] All percentages are out of the total n.
[b] Values are mean ± SD.

Healthy-group test-retest reliability values of the CAIT-I scores were excellent as well ($ICC_{2,1}$ = 0.92, 0.93, for left and right ankle, respectively) and item correlation was high for most of the items (ranging from $ICC_{2,1}$ = 0,75 to 0,86). The SEM were 2.67 (left ankle) and 3.06 (right ankle). MDC_{ind} were 7.4 for the left ankle and 8.5 for the right one, while MDC_{group} were 0.44 and 0.50 for the left and right leg, respectively.

Injured-group reliability was excellent for all CAIT-I scores ($ICC_{2,1}$ = 0.95 for the left ankle, 0.93 for right ankle), but there was more variability at an item level (correlations ranging from $ICC_{2,1}$ = 0.67–0.96). The SEM were 3.20 (left ankle) to 3.59 (right ankle). MDC_{ind} were 8.9 for the left ankle and 9.9 for the right one, while MDC_{group} were 0.52 and 0.59 for the left and right leg, respectively.

3.3. Construct validity

A combined subject pool comprising 550 participants was included in analyses of internal consistency, construct validity, sensitivity and factor analysis. Participants with incomplete questionnaires (more than 2 missing items) were deleted, resulting in 548 participants (97 %) (Table 2).

The group consisted of 46,7 % males and 53,3 % females, the 71,7 % of which reported to exercise regularly (at least 2–5 h/week).

Statistically significant linear Pearson correlations ($p < .001$) were

Table 2
Demographics (Validity, Factor Analysis, and ROC).

Demographic/Group	Male	Female	Total
Participants, n (%)[a]	256 (46.7 %)	292 (53.3 %)	548 (100 %)
BMI[b]	24.2 ± 2.9	22.1 ± 3.8	23.1 ± 3.5
Ankle Sprains in the last 3 months, n (%)[a]			
Yes	31 (12.3 %)	26 (8.9 %)	57 (10.3 %)
No	222 (87.7 %)	267 (91.4 %)	489 (89.7 %)
Lifetime Prevalence of Ankle Sprains, n (%)[a]			
1	50 (47.6 %)	55 (52.4 %)	105
2	37 (50.7 %)	36 (49.3 %)	72
> 2	88 (56.1 %)	69 (43.9 %)	157
Do you exercise regularly? N (%)[a]			
Yes	197 (79.4 %)	188 (65.1 %)	385 (71.7 %)
No	51 (20.6 %)	101 (34.9 %)	152 (28.3 %)
If Yes, which Sport do you practice? N (%)[a]			
Running	79 (59 %)	55 (41 %)	134
Jogging	46 (38.3 %)	74 (61.7 %)	120
Basketball	45 (63.4 %)	26 (36.6 %)	71
Volleyball/Beach Volleyball	18 (37.5 %)	30 (62.5 %)	48
Soccer	35 (79.5 %)	9 (20.5 %)	44
Yoga/Pilates	5 (11.9 %)	37 (88.1 %)	42
Others	143 (54.8 %)	118 (45.2 %)	261

[a] All percentages are out of the total n.
[b] Values are mean ± SD.

found both between the SF-36 PCS and CAIT-I total scores (r = 0.24 for left ankle and r = 0.27 for right ankle) and between the SF-36 MCS and CAIT-I total scores (r = 0.16 and 0.12 for left and right ankle, respectively) Table 3.

Individual items were compared to PCS domains (Physical Functioning, Role Physical, General Health, and Bodily Pain), with significant correlations ranging from $r = -0.35$ to -0.23 except for the last two items, who showed no statistically significant correlation.

More inconstant correlations were found between MCS domains (Vitality, Role Emotional, Social Functioning, and Mental Health), and individual CAIT-I items, with correlations ranging from $r = -0.20$ to 0.06, just few of which statistically significant.

3.4. Exploratory factor analysis and internal consistency

Data from the same group of 548 participants were used in EFA and to determine internal consistency (Cronbach's alpha). Initial parallel analysis produced a root-mean-square error of approximation of 0.08 and a Tucker-Lewis index of 0.92, with 2 factors and item loadings ranging from 0.51 to 0.78. The EFA was rerun, using Kaiser's criterion of eigenvalues greater than 1 point of inflection within a scree plot (Fig. 1), suppression of coefficients less than 0.30, and rotation to determine best fit using oblique Promax rotation for correlated variables [52].

Cut-off reflects point of inflection for eigenvalues greater than 1 (1 eigenvalue = 4.053).

Inter Item correlations loaded from 0.55 to 0.77 and resulted in two-factors loading (Table 4).

The Kaiser-Meyer-Olkin value was 0.87, indicating that data are appropriate, and sampling was sufficient. Also the Bartlett's Test of Sphericity was significant ($p < 0.001$), confirming that our example has patterned relationships. The two-factor loading accounted for 59 % of the common variance, with an eigenvalue of 1.255. Cronbach's alpha values were high for all 9 items if considered globally ($\alpha = .84$), and also if the left side ($\alpha = .84$), and the right side ($\alpha = .86$) were analysed separately.

Table 3
Validity Analysis of CAIT-I Versus SF-36.

Score	PCS	r[a]	MCS	r[a]
CAIT-I total left ankle	PCS[b]	0.24 (0.16, 0.32)	MCS[b]	0.16 (0.08, 0.25)
CAIT-I total right ankle	PCS[b]	0.27 (0.19, 0.35)	MCS[b]	0.12 (0.04, 0.21)
Item 1 left ankle	BP[b]	-0.17 (−0.25, −0.08)	VT[b]	-0.17 (−0.26, −0.09)
			RE	-0.11 (−0.19, −0.02)
			SF[b]	-0.16 (−0.24, −0,08)
Item 1 right ankle	BP[b]	-0.16 (−0.21, −0,08)	VT[b]	-0.18 (−0.27, −0.10)
			RE	-0.13 (−0.22, −0.05)
			SF	-0.10 (−0.19, −0.02)
Item 2 left ankle	PF[b]	-0.29 (−0.37, −0.21)	SF[b]	-0.16 (−0.24, −0.08)
Item 2 right ankle	PF[b]	-0.29 (−0.37, −0.21)	SF	-0.12 (−0.20, −0.03)
Item 3 left ankle	PF[b]	-0.30 (−0.38, −0.22)	SF[b]	-0.20 (−0.28, −0.11)
Item 3 right ankle	PF[b]	-0.33 (−0.41, −0.25)	SF	-0.10 (−0.18, −0.01)
Item 4 left ankle	PF[b]	-0.32 (−0.40, −0.24)	SF[b]	-0.19 (−0.28, −0.11)
Item 4 right ankle	PF[b]	-0.35 (−0.42, −0.27)	SF	-0.13 (−0.22, −0.05)
Item 5 left ankle	PF[b]	-0.23 (−0.31, −0.14)	SF	-0.08 (−0.16, −0.00)
Item 5 right ankle	PF[b]	-0.25 (−0.33, −0.17)	SF	-0.06 (−0.14, −0.02)
Item 6 left ankle	PF[b]	-0.25 (−0.33, −0.17)	SF[b]	-0.15 (−0.23, −0.06)
Item 6 right ankle	PF[b]	-0.27 (−0.35, −0.19)	SF	-0.08 (−0.16, −0.00)
Item 7 left ankle	PF[b]	-0.27 (−0.35, −0.19)	SF	-0.14 (−0.22, −0.05)
Item 7 right ankle	PF[b]	-0.30 (−0.38, −0.22)	SF	-0.06 (−0.16, −0.01)
Item 8 left ankle	RP	-0.01 (−0.10, 0.07)	MH	-0.04 (−0.12, 0.04)
	PF	-0.04 (−0.13, −0.04)	SF	-0.03 (−0.12, −0.05)
Item 8 right ankle	RP	-0.02 (−0.10, 0.07)	MH	-0.07 (−0.16, 0.01)
	PF	-0.03 (−0.11, −0.60)	SF	-0.05 (−0.14, −0.03)
Item 9 left ankle	PF	-0.03 (−0.11, 0.60)	MH	0.06 (−0.03, 0.14)
	GH	-0.01 (−0.10, 0.07)	SF	0.04 (−0.04, 0.13)
Item 9 right ankle	PF	-0.03 (−0.11, 0.06)	MH	0.02 (−0.06, 0.11)
	GH	-0.03 (−0.11, 0.05)	SF	0.02 (−0.07, 0.10)

Abbreviations: ADL, Activities of Daily Living; BP, Bodily Pain; CAIT-I Cumberland Ankle Instability Tool - Italian Version; GH, General Health; MCS, Mental Component Summary; MH, Mental Health; PCS, Physical Component Summary; PF, Physical Functioning; RE, Role Emotional; RP, Role Physical; SF, Social Functioning; SF-36, Medical Outcomes Study 36-Item Short-Form Health Survey; VT, Vitality.
[a] Values in parentheses are 95 % confidence intervals.
[b] Significant subscores (P < .001)

3.5. Sensitivity

Data from the same 548 participants were also used in sensitivity analyses. Significant differences were found between healthy (25.03 ± 4.91) and injured (21.90 ± 4.46) for CAIT-I score ($t_{564} = 4.59$, $P < .001$). Conversely, there were no statistically significant differences between groups for SF-36 PCS scores (healthy, 33.99 ± 2.57; injured,

Table 4
Factor Loadings.

Item Content	Factor 1	Factor 2	Uniqueness
Question n. 3	0.778		0.423
Question n. 2	0.750		0.396
Question n. 6	0.723		0.454
Question n. 7	0.723		0.489
Question n. 4	0.718		0.542
Question n. 1	0.573		0.634
Question n. 5	0.553		0.673
Question n. 9		0.699	0.518
Question n. 8		0.607	0.630

Note. Applied rotation method is Promax.

38.65 ± 2.34; t_{546} = 0.95, P = .34), and MCS scores (healthy, 16.61 ± 1.79; injured, 16.71 ± 1.78; t_{546} = −0.43, P = .67).

The ROC curves resulted in AUC values of 0.72 (95 % CI: 0.65, 0.78), suggesting an acceptable level of accuracy (Fig. 2).

Cut-off for the CAIT-I score was 24.75 (based on sensitivity and specificity values of 0.77 and 0.65, respectively). The LR+ value was 2.2 and the LR- 0.35.

3.6. Internal responsiveness

Thirty-eight participants (18 females, 20 males), who had sustained a total of 42 ankle sprains (between 1 and 2 sprains each) were used for the internal responsiveness measure.

A one-way repeated measures analysis of variance (ANOVA) was conducted to evaluate the null hypothesis according to which there was no change in participants' scores when measured in four different time points over a maximum of 12 months' time. We found significant evidence to reject the null hypothesis. Mauchly's Test of Sphericity indicated that the assumption of sphericity had been violated, and therefore a Greenhouse-Geisser correction was used (ε = .65). The results of the ANOVA indicated significant differences across time for CAIT-I scores, ($F_{(3, 196)}$ = 34.66, p < .001). Pairwise comparisons were also significant for $T_{injured}$ scores if compared with all the other time-points (p < 0.001), but not between $T_{healthy}$ versus T_2 or $T_{discharge}$, as supposed.

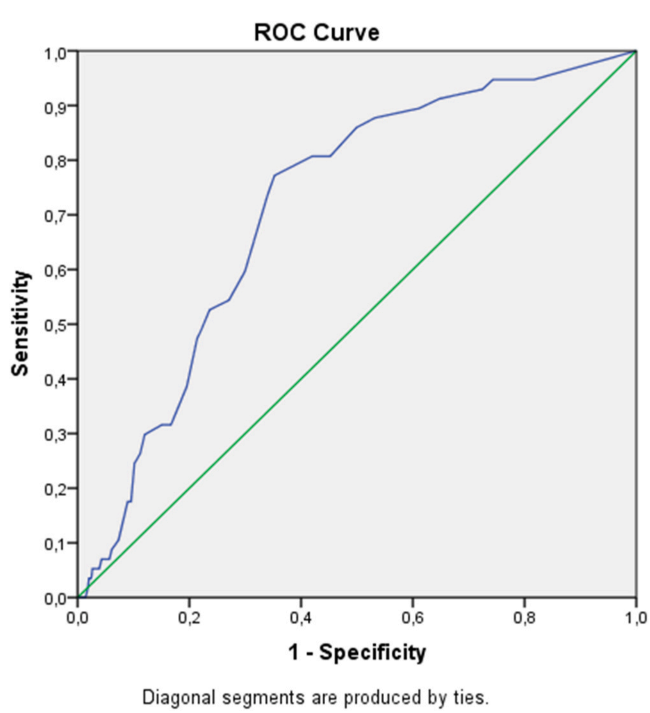

Fig. 2. Receiver Operating Characteristic curve.

See Table 6 – Supplementary Material - Responsiveness of the CAIT-I and SF-36.

3.7. Floor and ceiling effects

Within the injured group, CAIT-I scores were examined for floor and ceiling effects. Five percent (3/57) of injured individuals had the maximum CAIT-I score, and none had the minimum score. Therefore, no ceiling or floor effects were considered to be present [51].

4. Discussion

This study successfully cross-culturally translated the CAIT into Italian using robust methodology. Psychometric testing demonstrated excellent test-retest reliability, very good internal consistency, and fair construct validity, with an acceptable cut-off score of 25 and no floor or ceiling effects. This is highly relevant, because, for Italian speakers, no such tool aimed at assessing people's perception of instability was yet available.

Cross-cultural adaptation required a 4-steps process that followed the recommended methodology and guidelines [13,33]. We deemed the original version of the CAIT suitable for the Italian cultural background, so we did not need major adaptations of thecontent of the questions. Indeed, during the pilot testing, only minor issues arose, and, to maintain uniformity with the original questionnaire, only slight adaptations were made.

This CAIT validation has been tested in the widest cohort of participants ever. With 548 participants, we largely exceeded all the other available versions of the CAIT in terms of population tested, including the original one, that involved 236 participants which, until our Italian version, represented the largest cohort used [12]. Given the telematic method used for administering the questionnaire, our choice of not limiting the testing sample to the number obtained from the sample size calculation but involving the largest possible number of participants, did not represent an extra-cost for the study, and allowed a greater degree of confidence in the results achieved.

The participants who reported at least one episode of ankle sprain in the past and who experienced instability of the ankle and/or feeling of the ankle giving way during the last three months reported significantly lower total scores on the CAIT-I compared to those who did not, confirming the ability of the questionnaire to discriminate between the two.

The CAIT-I showed psychometric properties comparable to the original English version [12] and its available translations. In fact, its test–retest reliability was excellent ($ICC_{2,1}$ = 0.93 for both the left and right ankle), and this is in line with previously obtained results, ranging from 0.80 of the Urdu [24] to the 0.98 of both the Arabic [16] and one of the two Spanish [14] versions. We chose a 4–9-day time interval for test–retest reliability assessment, considering it as more appropriate, compared to the two weeks used by the original English validation [12] and the three weeks used in the Japanese one [21], because the patients' functional status and daily life do not dramatically change in 4–9-days interval, and such interval is long enough to assure that specific answers of the first administration would not be remembered.

The SEM values were 2.80 (for the left ankle) and 3.12 (for the right ankle) and these data confirm that the CAIT-I can be considered as a reliable and stable instrument for the assessment of CAI, with better values than other Italian validated musculoskeletal questionnaires [53].

The MDC provides a value for the minimum change that must be considered in order to be confident that this change is real and not a potential product of measurement error in instrument [54]. The MDC has been calculated for both individual participants (MDC_{ind}) and for comparisons of mean scores between groups (MDC_{group}) because both scores are useful in different contexts. In fact, the MDC_{ind} can be used in clinical practice and to label individual participants in a study sample as either 'changed' or 'unchanged', while MDC_{group} provides a guide to the interpretation of mean scores of groups. This could empower the results of interventional trials that will use the CAIT-I questionnaire, assessing whether the participants' perception of instability has changed in the intervention and control group as a whole. For CAIT-I MDC_{ind} were 7.8 for the left ankle and 8.6 for the right one, while MDC_{group} were 0.43 and 0.51 for left and right leg, respectively.

Cronbach's alpha values were high for all 9 items of CAIT-I if considered globally ($\alpha = .84$), and also if the left side ($\alpha = .84$) and the right side ($\alpha = .86$) were analysed separately. This result indicates very good internal consistency. Indeed, the results of the present study are consistent with those in the original version of the CAIT, in which the Cronbach's α was 0.83 [12], compared to the 0.85 mean value attained in the present study, and also in line with the data reported by all the other available translations, ranging from 0.76 in one of the two Spanish versions [14], to the 0.98 in the Arabic one [16].

In construct validity evaluation, the exploratory factor analysis reported a two-factors structure explaining 59 % of the variance. A two-factors structure was also reported in the original English version [12], as well as in the Korean [17] and Persian [22] translations. Among the few other validation studies which performed this analysis (5/14), the Arabic version [16] reported a single-factor structure, while the Urdu [24] and one of the Spanish translations[14] reported three different factors. In the Italian version, factor analysis reported that seven (out of nine) items loaded into the same factor, while items 8 and 9 produced independent factors. A possible explanation, in our case, might be that items 1–7 refer to everyday subjective sensations, therefore they concern more recent and clearer memories. On the contrary, items 8 and 9 do not refer to a well-defined movement, that the participant can easily recall, but rather to a hypothetical context. Indeed, the former (item 8) refers to a perception linked to a mostly instinctive and non-voluntary movement - i.e., not allowing the ankle to roll over right after this motion has begun - and the latter (item 9) to the timing between an episode of ankle rolling and the perception of it being back to normal. This not only refers back to a hypothetical situation, but it also involves a less conscious context compared to the one presented in all the other items. This might explain why it could be more easily subject to recall bias [55]. All remaining items of the questionnaire are related to more physical sequelae after daily and sports activities (items 1–7). These different situations may be perceived in a different way by the patients.

Construct validity was assessed using the Pearson correlation coefficient between the SF-36 summary components and the CAIT-I. We decided not to use the Italian version of the Lower Extremity Functional Scale (LEFS-I) [56] as a comparator for convergent validity assessment because the Italian version of the LEFS was validated in a cohort of 250 participants of which only 8 with foot conditions, so we were not confident in considering it an appropriate reference for this instrument. Similarly, we did not use the Foot and Ankle disability Measure (FAAM), because only one of its two subscales have been translated into Italian [53]. To this day, we have no other questionnaire in Italian assessing foot perception of instability or other related symptoms. Therefore, we deemed it appropriate to use SF-36 as comparing tool, because it has strong literature supporting its use with multiple diagnoses, disease severities, and musculoskeletal injuries. Moreover, it is frequently used as the principal measure for comparisons with new instruments, like the LEFS itself, and it has two different components, of which one demonstrated acceptable construct validity compared to lower extremity instruments, while the other divergent evidence.

Our results showed a stronger correlation with the physical component than with the mental component of the SF-36. This is in line with other studies, which suggested that physical function and pain dimensions of SF-36 seem to be most relevant on outpatients with musculoskeletal conditions [56].

We could not assess CAIT-I criterion validity, defined by the COSMIN group as the degree to which the scores of a patient related outcome (PRO) instrument are an adequate reflection of a 'gold standard' [57], because there is no gold standard for PROs instruments nor for assessing personal perception of instability.

Our sample allowed us to calculate a cut-off score for functional ankle instability, as has been previously done for the English original [12], and for other seven translated CAIT versions [16,18–21,23,26]. Cut-off for the CAIT-I score was 24.75 (based on sensitivity and specificity values of 0.77 and 0.65, respectively, with a LR+ value = 2.2 and LR- value = 0.35; this cut-off can be used to establish functional ankle instability in Italian speaking patients. The different CAIT versions obtained different cut-off scores to determine CAI, ranging from 11 in the Dutch version [18] to 27.5 in the original English version [12] (later revised in 25) [27]. Likelihood ratios are closely linked to cut-off scores and constitute one of the best ways to measure and express diagnostic accuracy. According to estimates independent of pre-test probability [58], the finding of LR+ of 2.2 increases the probability of having ankle instability of about 15 %, and an LR- of 0.35 decreases probability of having ankle instability of about 25 %.

We did not find any floor or ceiling effect for the total score of the CAIT-I, as expected from previous validations. The CAIT-I also demonstrated good acceptability, requiring only few minutes to be completed.

4.1. Limitation

There were some limitations in the current study. First of all, in order to compare 'healthy' and 'injured' participants for reliability and sensitivity analyses, we choose to qualify as 'injured' anyone who experienced both at least an episode of ankle sprain during their lifetime and the perception of ankle instability and/or feeling of the ankle giving way in the last 3 months. This choice was made in the attempt to be as precise as possible, and we intentionally excluded from the definition of "injured" those who had previously had history of ankle sprains but, currently, have no instability symptoms. This choice might be questioned, because it is not fully correct to define 'healthy' anyone who might have had recurrent ankle sprains in the past but has not had any self-perception of instability in the last three months. For internal responsiveness analysis, different time points were needed to be able to predict change in the construct of interest involving at least part of the study population. Therefore, in our analysis, we included only participants who were considered 'healthy' in the first administration of the test, but who later reported an episode of ankle sprain followed by symptoms of instability, and we followed these participants until their discharge from the rehabilitation programme. By doing so, we could have erroneously associated the use of this tool to an acute event, when, actually, the CAIT was not developed for people with acute sprains. Future studies should better select participants with a proper objective assessment made by a specialized clinician, in addition to a subjective one.

We tested the CAIT-I in a cohort of adults, mainly active participants, but not highly trained athletes. The extent to which our results can be generalized to sedentary, young people, or to professional athletes is unknown. However, since this was the first validation of the CAIT in Italian language, we decided to select a cohort that better reflected the patients with symptoms of ankle instability that we see daily in our clinical practice Future studies should better investigate the use of this instrument in more specific populations.

4.2. Strength

The main strength of this study lies in the rigorous methodology used to produce the Italian translation of the CAIT, ensuring its equivalence to the original English version. Another strength is the completeness of its validation, that also produced a cut-off score, LR+ and LR- values, a value for the SEM, and one for the MDC. Good psychometric properties and the ability to identify subtle changes in patients' status over time make the Italian version of the CAIT a useful tool in CAI management. Indeed, it is a fast and easily applicable instrument that will allow clinicians to assess the effectiveness of treatment, providing immediate feedback on the patient's ankle status and enabling the development of therapeutic strategies. Finally, our cohort of 528 participants corroborates the results of the present study.

The CAIT-I can also provide Italian researchers with a valid tool for research on ankle instability, a very common health problem in the Italian population.

5. Conclusion

This study described the development of translation, cultural adaptation, reliability and validity study of the Italian version of the CAIT, which is expected to improve instability detection, timely triage, and intervention in active people and general population, optimizing their recovery, performance, and well-being. The CAIT-I was successfully translated into Italian, showing good psychometric properties, replicating the results of the original and other versions of this questionnaire. Its use is recommended to help clinicians assessing the presence and severity of CAI. It will also assist researchers in comparing and sharing their results.

Brief summary

What Is Already Known

- Chronic ankle instability is a common cause of disability both in athletes and in general population, causing negative sequelae, from lowered quality of daily life to dysfunctional performance and could also lead to post-traumatic osteoarthritis.
- The Cumberland Ankle Instability Tool (CAIT) has proved to be a useful diagnostic instrument to discriminate between patients with simple ankle sprain issues and patients with chronic ankle instability.
- Currently, there is no Italian version of the CAIT.

What This Study Adds

- The Italian Version of the Cumberland Ankle Instability Tool (CAIT-I) demonstrated good psychometric performance as a screening and outcome measure for adult, active population.
- CAIT-I demonstrated excellent reliability along with good sensitivity, internal responsiveness, and validity when compared to the Medical Outcomes Study 36-Item Short-Form Health Survey, with a cut-off score of 24.75.

CAIT-I is a useful tool to assess and monitor chronic ankle instability in an Italian speaking population.

CRediT authorship contribution statement

AS and FB contributed to the conception of the work. CV and PP provided the process of obtaining ethical approval and registration. AC developed the study design and analysed the data, with the support of MG. She also drafted the first version of the manuscript, with input from all authors, especially of GD for the background and both MG and CV for the discussion. All authors helped with data collection, reviewed and edited the manuscript, and approved the final version of it.

Declaration of Competing Interest

All authors declare that they have no conflicts of interest.

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Appendix A

QUESTIONARIO CAIT.
Per OGNI domanda, seleziona UNA SOLA affermazione, quella che MEGLIO descrive le tue caviglie.

	Caviglia SINISTRA	Caviglia DESTRA	Punteggio
1. Provo dolore alla caviglia			
Mai	☐	☐	5
Quando faccio sport	☐	☐	4
Quando corro su superfici irregolari	☐	☐	3
Quando corro su superfici piane	☐	☐	2
Quando cammino su superfici irregolari	☐	☐	1
Quando cammino su superfici piane	☐	☐	0
2. Percepisco la caviglia INSTABILE			
Mai	☐	☐	4
A volte quando faccio sport (ma non sempre)	☐	☐	3
Tutte le volte che faccio sport	☐	☐	2
A volte durante le attività quotidiane	☐	☐	1
Frequentemente durante le attività quotidiane	☐	☐	0
3. Quando faccio BRUSCHI cambi di direzione, percepisco la caviglia INSTABILE			
Mai	☐	☐	3
A volte quando corro	☐	☐	2
Spesso quando corro	☐	☐	1
Quando cammino	☐	☐	0
4. Quando scendo le scale, percepisco la caviglia INSTABILE			
Mai	☐	☐	3
Se scendo rapidamente	☐	☐	2

(*continued on next page*)

(*continued*)

	Caviglia SINISTRA	Caviglia DESTRA	Punteggio
A volte	☐	☐	1
Sempre	☐	☐	0
5. Quando sto in piedi su UNA SOLA gamba, percepisco la caviglia INSTABILE			
Mai	☐	☐	2
Se poggio sull'avampiede	☐	☐	1
Se poggio su tutta la pianta del piede	☐	☐	0
6. Percepisco la caviglia INSTABILE			
Mai	☐	☐	3
Quando saltello da una parte all'altra	☐	☐	2
Quando saltello sul posto	☐	☐	1
Quando salto in generale	☐	☐	0

7. Percepisco la caviglia INSTABILE			
Mai	☐	☐	4
Quando corro su superfici irregolari	☐	☐	3
Quando corro a velocità moderata su superfici irregolari	☐	☐	2
Quando cammino su superfici irregolari	☐	☐	1
Quando cammino su superfici piane	☐	☐	0
8. GENERALMENTE, quando sento che mi si gira la caviglia, riesco a evitare che succeda			
Subito	☐	☐	3
Spesso	☐	☐	2
A volte	☐	☐	1
Mai	☐	☐	0
Non mi si è mai girata la caviglia	☐	☐	3
9. Dopo una COMUNE distorsione, la mia caviglia torna "normale"			
Quasi immediatamente	☐	☐	3
In meno di un giorno	☐	☐	2
Dopo 1–2 giorni	☐	☐	1
Dopo più di 2 giorni	☐	☐	0
Non mi si è mai girata la caviglia	☐	☐	3

NOTA: il punteggio si trova nella colonna più a destra e non è visibile nel questionario fornito al soggetto in esame.

Appendix B

Translation and Cross-Cultural Adaptation.

The doubts that arose during the discussion by the working group during Step 2 of the cross-cultural adaptation process were analysed and solved as follows:

- in *Appendix 1*, "Per OGNI domanda seleziona l'affermazione che." has been translated as "Per OGNI domanda, seleziona UNA SOLA affermazione, quella che.";
- in item 4, "Se scendo velocemente" has been replaced with "Se scendo rapidamente";
- in item 6, "Quando saltello da un lato/piede all'altro" has been changed with "Quando saltello da una parte all'altra";
- in item 8, "TIPICAMENTE, quando sento che mi si gira la caviglia, riesco a fermarla" has been phrased with "GENERALMENTE, quando sento che mi si gira la caviglia, riesco a evitare che succeda";
- in item 9, "Dopo un TIPICO incidente di distorsione" has been replaced with "Dopo una COMUNE distorsione, la mia caviglia torna "normale";
- also in item 9, "Non mi sono mai storto/a la caviglia" has been changed with "Non mi si è mai girata la caviglia";
- in the final footnote, "Il sistema di attribuzione dei punti non è visibile nel questionario del soggetto preso in esame" has been replaced with "il punteggio si trova nella colonna più a destra e non è visibile nel questionario fornito al soggetto in esame".

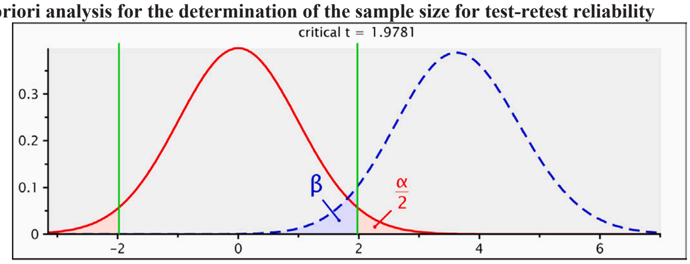
After receiving comments on some elements during Step 5 of the cross-cultural adaptation process, the pre-final version test, the following changes were unanimously made:

- in item 6: "quando saltello da una parte all'altra" has been replaced with "quando saltello da una parte all'altra sullo stesso piede";
- in item 6 "quando saltello sul posto" has been changed with "quando saltello sul posto sullo stesso piede";
- in 'item 8 "GENERALMENTE, quando sento che mi si gira la caviglia." has been replaced with "GENERALMENTE quando sento che mi si sta per girare la caviglia.";
- in item 9 "Dopo una COMUNE distorsione." has been phrased with "Dopo una TIPICA distorsione.".

Appendix C

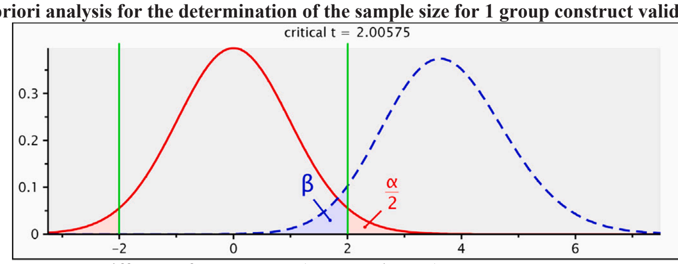
A priori analysis for the determination of the sample size for test-retest reliability.

A priori analysis for the determination of the sample size for test-retest reliability



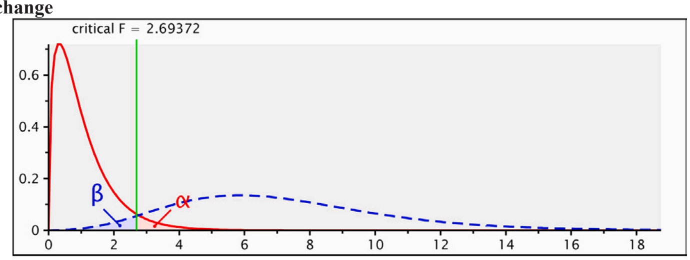
t tests - Correlation: Point biserial model
Analysis: A priori: Compute required sample size
Input parameters: Tail(s) = Two
 Effect size |ρ| = 0.3
 α err prob = 0.05
 Power (1-β err prob) = 0.95
Output: Noncentrality parameter δ = 3.6404323
 Critical t = 1.9780988
 Df = 132
 Total sample size = 134
 Actual power = 0.9509217

A priori analysis for the determination of the sample size for 1 group construct validity



t tests - Means: Difference from constant (one sample case)
Analysis: A priori: Compute required sample size
Input parameters: Tail(s) = Two
Effect size d = 0.5
α err prob = 0.05
Power (1-β err prob) = 0.95
Output: Noncentrality parameter δ = 3.6742346
Critical t = 2.0057460
Df = 53
Total sample size = 54
Actual power = 0.9502120

A priori analysis for the determination of the sample size for instrument responsiveness to change



ANOVA: Repeated measures, within factors
Analysis: A priori: Compute required sample size
Input parameters: Effect size f = 0.25
α err prob = 0.05
Power (1-β err prob) = 0.95
Number of groups = 2
Number of measurements = 4
Corr among rep measures = 0.5
Nonsphericity correction ε = 1
Output: Noncentrality parameter λ = 18.0000000
Critical t = 2.6937209
Denominator Df = 102
Total sample size = 36
Actual power = 0.9517650

Appendix D. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.foot.2023.102043.

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